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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) MSDI-269/PC545.02	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>September 15, 2008</u> Signature <u>Douglas A. Collier</u> Typed or printed name <u>Douglas A. Collier</u>		Application Number 10/689,277 First Named Inventor Eddie F. Ray III Art Unit 3733	Filed October 20, 2003 Examiner Jerry L. Cumberledge
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>43,556</u> <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		<u>Douglas A. Collier</u> Signature <u>Douglas A. Collier</u> Typed or printed name <u>(317) 238-6333</u> Telephone number <u>September 15, 2008</u> Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:)	Before the Examiner:
Eddie F. Ray III)	Jerry L. Cumberledge
)	
Serial No.: 10/689,277)	Group Art Unit: 3733
)	
Filed: October 20, 2003)	Attorney Docket: MSDI-269/PC545.02
)	
METHODS AND INSTRUMENTATION)	September 15, 2008
FOR VERTEBRAL INTERBODY)	
FUSION)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Alexandria, VA 22313-1450

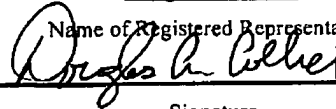
In response to the Final Office Action dated June 13, 2008, and Advisory Action mailed August 18, 2008, please consider the following. A Notice of Appeal, and form PTO/SB/33 Pre-Appeal Brief Request for Review is submitted herewith along with the fee under 37 CFR 41.20(b)(1). No extensions of time are believed due. However, please provide any extensions of time that may be necessary and charge any additional fees due, or credit any overpayment, to Deposit Account 12-2424, but not including the payment of issue fees.

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at 571-273-8300 on:

September 15, 2008
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Douglas A. Collier

Name of Registered Representative



Signature

September 15, 2008
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REMARKS

The present application includes claims 1-6, 8-19, 27-32 and 34-38 pending and which stand rejected in the Final Office Action mailed June 13, 2008. Reconsideration of the Final Office Action was requested in a response filed on July 31, 2008. A response to the November 29, 2007, non-Final Office Action was filed on February 28, 2007. This Pre-appeal Brief Request for Review is being submitted since it is believed that a prima facie case for finally rejecting the claims has not been established.

Claims 27-32, 34, and 35 stand rejected under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,505,732 to Michelson alone. Arguments with respect to these rejections are of record in the July 31, 2008 response beginning at page 2, second paragraph through the first full paragraph on page 4, and in the February 28, 2008 response, beginning at page 8, second paragraph to the first full paragraph on page 10.

Claim 27 recites the surgical instrument includes the following elements: 1) a shaft with an engaging portion at a distal end of the shaft and the engaging portion has an enlarged configuration extending outwardly from the shaft; 2) a distractor tip that extends distally from the enlarged engaging portion; 3) a member that is a guide sleeve housing with a proximal portion defining a chamber and a distal portion defining first and second access ports; and 4) the enlarged configuration of the engaging portion at the distal end of the shaft is sized and shaped to fit in the proximal chamber of the guide sleeve housing with a close interfit to provide a rigid assembly between the engaging portion and the guide sleeve housing.

The Examiner asserts tubular portions 348 in Fig. 7F are a shaft, some portion of Fig. 7F near footplate 344 is an engaging portion at the distal end tubular portions 348, and that footplate 344 is a guide sleeve housing with a proximal and distal chamber. See page 5, lines 9-18 of the Final Office Action. The Examiner also asserts that the engaging portion of tubular portions 348 near footplate 344 include an enlarged configuration that extends outwardly from tubular portions 348 and the distal tip 102. The Examiner has not identified any structure that teaches or suggests an engaging portion at the distal end of tubular portions 348 having an enlarged configuration that extends outwardly from both tubular portions 348 and distractor tip 102. If footplate 344 is considered the engaging portion with the enlarged configuration, then it cannot be properly considered to correspond to the guide sleeve housing of claim 27 since claim 27

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makes clear "said enlarged configuration being sized and shaped to fit in said proximal chamber" of the guide sleeve housing. Footplate 344 cannot be both the engaging portion with the enlarged configuration and also the guide sleeve housing with the proximal chamber since it is not possible for footplate 344 to both define a chamber and also be sized and shaped to fit in the chamber in which it defines. In reply to applicants' arguments submitted in the response filed February 28, 2008, the Examiner asserts that the portion with the enlarged configuration, presumably tubular portions 348, once separated from the device, presumably footplate 344, would be capable of being wedged or forced into at least a portion of the proximal chamber to create such a fit. As discussed above, in Fig. 7F the Examiner has failed to identify any portion of tubular portions 348 near footplate 344 that is enlarged to extend outwardly from tubular portions 348 that is also sized and shaped to fit in a proximal chamber of the footplate 344 as is defined for the engaging portion in claim 27.

The Examiner also asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to have separated what can be considered to be the guide sleeve assembly (namely ref. 344) from the guide sleeve, ref. 348) (sic), since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179." The Examiner fails to explain or cite any prior art teaching that would have fairly suggested, to one of ordinary skill in the art, the desirability of making tubular portions 348 releasably engageable from footplate 344. While the Examiner notes that Michelson teaches connection mechanisms at col. 2, lines 6-11, as explained previously, the cited portion of Michelson is discussing techniques for securing collar 248 to drill 240 in a lockably adjustable manner. The Examiner has pointed to no teaching that such mechanisms are employed to secure tubular portions 348 to footplate 344, or any teaching or suggestion of how such a connection arrangement could be configured with tubular portions 348 and footplate 344 to teach or suggest claims 31 and 32.

Furthermore, the Examiner appears to equate "a flange and groove" disclosed in Michelson for lockably adjusting a drill to a sleeve to the finger and receptacle of claim 31. Claim 31 states the finger and receptacle are part of the engaging portion at the distal end of the shaft and the finger is movable out of the receptacle to engage the guide sleeve housing and movable into the receptacle to release the guide sleeve housing. The Examiner has failed to

explain, nor is it not understood how one of ordinary skill in the art would have any reason to modify tubular portion 348 to include "a receptacle formed therein and a finger movable out of said receptacle to an engagement position wherein said finger engages said guide sleeve housing in said proximal chamber and wherein said finger is movable to a release position into said receptacle to release said guide sleeve housing from said engaging portion" based on Michelson's disclosure of lockably adjusting a drill to a sleeve with "flanges engaging grooves forced therein by either a cap pulled over the flanges or screwed down upon them". Claim 32 depends from claim 31 and further defines the distractor tip as having a distraction configuration which positions the finger in the engagement position and the distractor is rotatable to a reduced height configuration to move the finger to a release position. With regard to claims 31 and 32, it is clear that the structural attributes of the claimed component parts and their interrelation as defined by the functional limitations are not disclosed or taught in the cited references.

Claims 1-6, 8-19 and 36-38 were rejected under 35 USC §103(a) as unpatentable over Michelson in view of U.S. Patent No. 5,055,104 to Ray. Arguments with respect to these rejections are of record in the July 31, 2008 response beginning at page 4, last paragraph through the last paragraph on page 5, and in the February 28, 2008 response, beginning at page 10, first full paragraph to the first full paragraph on page 13.

The Examiner responds to Applicants' previous arguments with respect to the distractor in the cited references not being located in a location between the ports by asserting that this is a functional clause and the device must merely be capable of performing such a function. It is respectfully submitted that the Examiner has failed to point out how the cited references are even capable of functioning as claimed. Michelson discloses tubular portions 348 that form separate ports that each has a wall extending therearound, with the walls separated by an area 350 at a location between the ports. See col. 28, lines 8-12. Footplate 344 includes a wall at a location between each of the ports extending therethrough: See Fig. 7C. In maintaining the final rejection, the Examiner asserts that since the distractor tips are located between the lateral most portions of the ports the distractor tips 102 can be considered to be located between the ports. However, even if the distractor tips are between the lateral most portions of the ports of tubular portions 348, neither is "movably positionable from a location between said first and second working channel ports..." as recited in claim 1. Claim 1 specifies the location of the distractor is

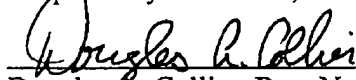
between the ports, and any location entirely within one port or the other port is not between the ports, but rather is a location within the port. In order support the rejection, it appears the Examiner is ignoring the limitations that specify the location is between the ports, and improperly broadening the limitation to construe that the location is between lateral most portions of the ports in order to support the rejection. Michelson discloses distractors within one port and/or the other port, but not in a location between the ports since the walls of tubular portions 348 and footplate 344 occupy that space. Since distractor tips 102 are not capable of being movably positionable from area 350 between tubular portions 348 or through the central wall of footplate 344, and since Ray does not address these deficiencies, it is respectfully submitted that a prima facie case for rejecting claim 1 has not been established.

Claim 36 recites, among other features, "said central distractor including a distractor tip at a location between said first and second working channel ports". It is clear that this is not a functional clause since it positively recites the location of the distractor tip relative to the working channel ports. Second, as discussed above with respect to claim 1, this arrangement of elements is not disclosed or suggested in the cited references.

The Office Action also fails to provide a prima facie case for rejecting claims depending from claims 1 and 36. For example, claims 9 and 10 are allowable for reasons provided above with respect to claims 31 and 32. Claims 3, 8 and 11 are allowable for reasons provided in the February 28, 2008 response.

In view of the foregoing remarks, it is respectfully submitted that a prima facie case for rejecting pending claims 1-6, 8-19, 27-32 and 34-38 has not been established. Withdrawal of the Final Rejection and allowance of the present application is respectfully requested.

Respectfully submitted,



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